

REMARKS

Reconsideration and withdrawal of the rejections of the application is respectfully requested in view of the remarks and amendments herein. The Examiner is thanked for withdrawing the art rejections over Wardley and Mazzara.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 21-31 are now pending. Claims 26-31 have been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply to round out the scope of protection to which Applicant is entitled.

II. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claims 21-25 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly lacks enablement for inducing a cellular immune response when administering a naked plasmid construct comprising gp120 or for inducing any immune response against FIV when administering a naked plasmid construct comprising gag and pro in the absence of env. The rejection is respectfully traversed.

35 U.S.C. §112, first paragraph, requires that the specification describe how to make and use the invention. 35 U.S.C. §112, first paragraph, recites, in pertinent part:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.]

A patent claim is invalid if it is not, *inter alia*, supported by an enabling disclosure. The test for enablement requires a determination of whether any person skilled in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 8

U.S.P.Q.2d 1400, (Fed. Cir. 1988). The factors involved in determining whether there is sufficient evidence to support a finding of enablement include, among others, (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the level of one of ordinary skill, (5) the level of predictability in the art, (6) the amount of direction provided by the inventor, (7) the existence of working examples, and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *See Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404.

It is respectfully submitted that the present application satisfies the enablement requirement as described above.

The Office Action indicates that "[t]he state of the art shows that inducing a humoral immune response against FIV env is possible when administering a naked plasmid that encodes env protein". Office Action at 4, citing Cuisinier *et al.* Further, the Office Action states that the immune response induced was a humoral immune response. Office Action at 5.

Initially, Applicants respectfully assert that "the state of the art" cannot be based on Cuisinier *et al.* alone. And, even if Cuisinier *et al.* is considered "the state of the art", there is nothing in Cuisinier that teaches away from the induction of an immune response with a naked plasmid construct having one or more of gag or pol, without env.

Cuisinier *et al.* describes the administration of plasmids having the gp120 gene, and the reference itself indicates that "cats immunized twice with the gp120 gene showed different patterns after challenge." See Cuisinier, at abstract. Further, the only administration of the p10 gene occurred in cats already vaccinated with the gp120 gene. For this reason, Cuisinier cannot be considered to teach away from the administration of the p10 gene in the absence of the gp120 gene. Cuisinier did not attempt such an administration, nor is such an alteration of Cuisinier's protocol considered.

Instead, to determine the state of the art related to whether gag and/or pro can be effective in the absence of env, one would have to consider those references where gag and/or pro were administered without env, not merely after such an administration. For example, international patent application publication WO 98/21354 discusses the administration of gag and/or pr in the absence of env in, for instance, Example 7. At page 81, lines 1-4, WO 98/21354 states that "this data provides ... protection against FIV infection in cats using a subunit immunogen, including only the FIV gag-pr. In fact, the presence of Env may have reduced efficacy."

Although WO 98/21354 relates to recombinant expression vectors, such as recombinant ALVAC, instead of naked plasmids, WO 98/21354 cannot be overlooked in considering the state of the art. One of skill in the art would be aware of such a finding that gag and/or pro can be effective in the absence of env, and would likely consider other potential applications for such knowledge.

Therefore, the state of the art would not only lead one of skill in the art to develop a naked plasmid containing env or env in combination with gag and/or pol, but would also lead to considering the development of a naked plasmid containing gag and/or pol without env. Although such a development would not be obvious from WO 98/21354, WO 98/21354 must certainly be considered alongside Cuisinier as to the state of the art, which therefore leads to one of skill in the art being aware that any combination of env, gag and/or pol could be useful in a vaccine.

Furthermore, the present specification provides information relating to the development of the naked plasmids containing some combination of env, gag and/or pol, and further describes the vaccination process. Accordingly, contrary to the assertions of the office action, practicing the claimed invention will not necessitate undue experimentation on the part of the skilled artisan.

Consequently, as the pending claims are not unduly broad, the state of the prior art supports the use of any of env, gag and/or pol as immunogens, even when env is not present, the level of one of ordinary skill in the art is high, the level of predictability in the art is sufficient to avoid undue experimentation, the amount of direction provided by the inventor is high and includes direction for the preparation of the plasmids and the vaccination itself, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure is low, and is certainly not undue, the application is sufficiently enabled.

Reconsideration and withdrawal of the enablement rejections under 35 U.S.C. §112, first paragraph, is therefore respectfully requested.

III. THE REJECTION UNDER 35 U.S.C. §102 ARE OVERCOME

Claims 21 and 24 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Cuisinier *et al.* The rejection is respectfully traversed.

Cuisiniere *et al.* has a publication date of July 1997. The present application was filed August 30, 2001 as a divisional of US Patent Application No. 09/232,278 filed January 15, 1999, which application is a continuation-in-part of international patent application PCT/FR97/01315 filed July 15, 1997, and which claims priority to French application 96/09337 filed July 19, 1996. Both PCT/FR97/01315 and 96/09337 were originally filed in French, such that the present application has been accorded a priority date of January 15, 1999.

Applicants respectfully assert that the present application is entitled to a priority date of July 19, 1996. In order to verify the priority claim, Applicants are obtaining, and will provide under separate cover, a verified translation of the priority documents.

As review of the verified translation will result in the present application being afforded a priority date of July 17, 1996, which date is a full year prior to the publication date of Cuisiniere, Applicants respectfully submit that the art rejection based on Cuisiniere is improper and cannot stand.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested in view of the remarks above and the verified English translations of the priority documents, as provided under separate cover.

REQUEST FOR INTERVIEW

If any issue remains an impediment to allowance, a further interview with the Examiner is respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

Favorable reconsideration of the application as amended herein and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully Submitted,

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